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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/665,936	09/19/2003	Jack Chu	P1768 (MEDT/0024)	6819

28390 7590 04/26/2007

MEDTRONIC VASCULAR, INC.
IP LEGAL DEPARTMENT
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EXAMINER	
KENNEDY, SHARON E	

ART UNIT	PAPER NUMBER
1615	

SHORTENED STATUTORY PERIOD OF RESPONSE	NOTIFICATION DATE	DELIVERY MODE
3 MONTHS	04/26/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 04/26/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

rs.vasciplegal@medtronic.com

Office Action Summary	Application No.	Applicant(s)	
	10/665,936	CHU ET AL.	
	Examiner	Art Unit	
	Sharon E. Kennedy	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 February 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,4,6-12,15-19,55 and 73-76* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3, 4, 6-12, 15-19, 55, 73-76* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02 February 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 17-19 and 76 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 76 recites that the device is located within a blood vessel. This rejection has the same reasoning as set forth in the previous final rejection. To correct, application should amend the claim by inserting -- adapted to be-- before the word "located" in line 2 of the claim. Claims 17-19 have the same problem.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 17-19 and 76 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Regarding claim 76, this claim is confusing because it is unclear if the device has patent protection only when present inside a blood vessel or sac, or if the device has patent protection in commerce. Applicant claims the second end of the tubing as being "located within the blood vessel lumen or adjacent to the aneurysmal sac." It is assumed that applicant wants patent protection

for the device in commerce, accordingly, for the purposes of examination, the claim will be interpreted according to the examiner's suggested amendment above. Regarding claims 17-19, again, applicant claims the device implanted in the body. This rejection is repeated.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 74-76 are rejected under 35 U.S.C. 102(b) as being anticipated by Heil, Jr., US 5,041,107. Heil represents a large body of prior art dedicated to implantable pumps. Applicant claims a device for the treatment of aneurysmal tissue, however, nothing in the claims distinguishes over Heil in structure. It is well settled that the absence of a prior art disclosure to the function of the device does not defeat a finding of anticipation. See MPEP 2114. The relevant portion is reproduced below for applicant's convenience.

APPARATUS CLAIMS MUST BE STRUCTU-RALLY DISTINGUISHABLE FROM THE PRIOR ART

>While features of an apparatus may be recited either structurally or functionally, claims< directed to >an< apparatus must be distinguished from the prior art in terms of structure rather than function. >*In re Schreiber*, 128 F.3d 1473, 1477-78, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997) (The absence of a disclosure in a prior art reference relating to function did not defeat the Board's finding of anticipation of claimed apparatus because the limitations at issue were found to be inherent in the prior art reference); see also *In re Swinehart*, 439 F.2d 210, 212-13, 169 USPQ 226, 228-29 (CCPA 1971);< *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA 1959). "[A]pparatus claims cover what a device *is*, not what a device *does*." *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990) (emphasis in original).

The examiner did not find any disclosure applying any such implantable pump in aneurysmal tissue as intended by applicant's invention. Accordingly, it is suggested that applicant insert limitations which structurally distinguish applicant's aneurysmal pump from the prior art. Changing the preamble from a "device for treating aneurysmal tissue" to --an aneurysmal tissue treatment device--, and adding a limitation to the drug infused, would distinguish the device over the prior art. The language found on lines 6-9 of paragraph [0008] of applicant's published application, US 2003/0065593, would be appropriate for characterizing the delivered drug.

Claims 1, 3, 4, 6, 7, 9, 11, 12, 16, 18, 19, 73 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by McCrory et al., US 6,139,520. Note is made of applicant's characterization of "reservoir" in applicant's published paragraph [0008] of US 2005/0065593. Accordingly, the cross-linked polysaccharide fiber disclosed by McCrory meets the claimed limitations. Note that the device is useful in the treatment of

aneurysms, as stated by McCrory in column 1, line 44-45 and throughout the disclosure. See column 8, line 26, which discloses the placement of the implant. Time release is disclosed in McCrory claims 18 and 38 and column 5, line 30. Regarding claim 4, note that the fiber forms a hydrogel. See column 5, line 9, for the explicit disclosure. Regarding claim 7, note the composition of the second liquid. See column 3, lines 45+. Regarding claim 18, although the intended placement of a device is not accorded much patentable weight (applicant continues to confuse the different concepts between method and apparatus claims), McCrory explicitly discloses placement of the fibers inside the aneurysmal sac in column 8, lines 26-28. Regarding claim 19, clearly the McCrory can be used outside an aneurysmal sac. Regarding the claimed carrier material, again, the analysis of applicant's paragraph [0008] helps in determining the definition of "carrier," which is sometimes used interchangeably with the reservoir. The reservoir can be simply the therapeutic agent or the carrier can be a liquid. Note that the McCrory patent discloses a carrier comprising a liquid which is used to eject the preformed fiber, the fiber being the reservoir. Nothing in applicant's claims eliminates this possibility. Claim 12 is anticipated because the first McCrory material may be poly vinyl alcohol (column 5, line 44), cyanoacrylate adhesive (column 5, line 49) or polyacrylic acid (column 3, line 49), which meets the claimed synthetic biostable material. The second material may be cellulose, polysaccharide, etc.

Claims 1, 6, 7, 9, 10, 16-18, 55, 73 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Rosenbluth et al., US 2003/0014075. Note reservoir 30, shown in

various figures, and the compositions thereof set forth in paragraph [0054] +. A carrier is disclosed on [0066] with various physical characteristics.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 10 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over McCrory '520. Regarding claim 10, McCrory discloses polyacrylic acid. The specific acrylate polymers would be obvious in the absence of a showing of criticality. Regarding claim 15, McCrory does not disclose the specific drugs claimed but indicates that drugs appropriate for the treatment of aneurysmal tissue is preferred. Any drug that would be useful for this purpose is considered obvious.

Claims 55 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over McCrory '520 in view of Rosenbluth et al., US 2003/0014075. See especially figure 3 of Rosenbluth, exemplifying that it is well known to employ an aneurysmal sac-filling treatment which may contain drugs, with a stent graft to help hold the treatment gel in place. It would be obvious to the ordinary surgeon to apply any type of treatment agent with the Rosenbluth method as necessary for the patient, simply dependent on the type of aneurysm, the location of the aneurysm, the size and shape of the aneurysm, and other factors which affect the retention ability of the applied treatment agent.

Claims 3, 4, 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenbluth et al., '075 in view of Hubbell et al., US 5,410,016. Rosenbluth fails to disclose the specific reservoir polymers and does not explicitly state the reservoir is time release. Hubbell discloses time release, biodegradable poly lactic acid polymers, and others. It would be obvious to one of ordinary skill in the art to use the Hubbell polymers with the Rosenbluth device in view that Rosenbluth explicitly suggests the combination in [0065], line 4.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon E. Kennedy whose telephone number is 571/272-4948. The examiner can normally be reached on Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on 571/272-8373.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sharon E. Kennedy

Sharon E. Kennedy
Primary Examiner
Art Unit 1615